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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,945	08/23/2005	Andrea Capocchi	263361US0PCT	4907
22850 7590 05/21/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 05/21/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/516,945	Applicant(s) CAPOCCHI, ANDREA	
	Examiner Michael C. Henry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 11-23 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Objections

Claims 17 and 18 are objected to because of the following informalities: Claim 11 contains two periods. However, each claim should begin with a capital letter and end with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 11 recites the limitation "the hot solution" in step b). However, there is insufficient antecedent basis for this limitation in the claim. More specifically, there is no previous reference in the claim to the phrase "the hot solution."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al. (EP 0153998 A2).

In claim 11, applicant claims a process of lyophilization for the preparation of a piroxicam: β -cyclodextrin inclusion compound in a 1:2.5 molar ratio comprising the steps of: a) dissolving piroxicam and β -cyclodextrin in the molar ratio of 1 to 2.5 and ammonium hydroxide in water brought to a temperature of at least 60 °C; b) bringing the hot solution to the temperature of -10 °C of complete freezing; and c) drying the frozen solution under vacuum. wherein the temperature of -10 °C of complete freezing of the hot solution of step a) is achieved at a cooling rate equal to or higher than 1 °C/min. Dependent claims 12-16 and 19-21 are drawn to the use of specific temperatures and cooling rates. Claims 17 and 18 are drawn to said method wherein the hot solution is specifically cooled or freezed by liquid nitrogen and the product is obtained in specific form. Claim 22 is drawn said method involving the use of specific % concentration weight ratio r of ammonium hydroxide to the Claim 23 is drawn to said method with specific time of achieving the temperature of freezing the hot solution.

Chiesi et al. disclose a process of lyophilization for the preparation of a piroxicam; β -cyclodextrin inclusion compound in a 1:2.5 molar ratio (0.088:0.220 moles) comprising dissolving piroxicam and β -cyclodextrin in the molar ratio of 1 to 2.5 and 30% ammonium hydroxide in water brought to a temperature of 60 °C; bringing the hot solution to the temperature of -20 °C of complete freezing and drying the frozen solution under vacuum (freeze drying) (see pages 3-4, example 4). It should also be noted that applicant further claims a lowering of temperature of their solution to a temperature -20 °C which is the same temperature to which Chiesi et al. lowers their solution (see applicant's, claim 15).

The difference between applicant's claimed method and the method of Chiesi et al. is that applicant freezes or cools their solution to a temperature of -10 °C whereas Chiesi et al.'s freezes or cools their solution to a temperature of -20 °C, and Chiesi et al.'s is silent about the rate of cooling or freezing rate of said solution. However, Chiesi et al.'s disclose that their solution can be freeze dried in general and thus a skilled artisan would be motivated to adjust the physical parameters used in Chiesi et al.'s method such as temperature so as to optimize the reaction conditions and/or based on factors such as availability or need. Also, even if the rate of cooling or freezing was different, the rate of cooling or freezing should not affect the product formed especially since applicant's claimed lyophilized product is the same as Chiesi et al.'s lyophilized product and since they both used the same reactants to produce their said lyophilized product.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Chiesi et al., and to make adjustments to condition parameters like the temperature and the rate of cooling or freezing in order to prepare Chiesi et al.'s composition, to treat arthro-rheumatic diseases.

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One having ordinary skill in the art would have been motivated, to use the process of Chiesi et al., and to make adjustments to condition parameters like the temperature and the rate of cooling or freezing in order to prepare Chiesi et al.'s composition, to treat arthro-rheumatic diseases, because a skilled artisan would reasonably be expected to adjust said parameters so as to optimize the reaction conditions and/or based on factors such as availability or need. It should be noted that a skilled artisan would be motivated to adjust the physical parameters used in Chiesi et al.'s method such as temperature, the manner of cooling and rate of cooling the solution so as to optimize the reaction conditions and/or based on factors such as availability or need.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Michael C. Henry

SAD 5/11/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

May 11, 2007.